Bering Ltd
% Stephan Toupin - Official Correspondent
Dawa Medical LLC
7320 NW 12th Street Suite 103
Miami, FL 33126

November 9, 2023

Re: K223754
Trade/Device Name: BraveCX
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological Computer Aided Triage And Notification Software
Regulatory Class: Class II
Product Code: QFM
Dated: October 11, 2023
Received: October 11, 2023

Dear Stephan Toupin:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download). Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100,

Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica Lamb
Assistant Director
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223754

Device Name
BraveCX

Indications for Use *(Describe)*
BraveCX is a radiological computer-assisted triage and notification software that analyzes adult (≥18 years old) chest X-ray images for the presence of pre-specified suspected critical findings (pleural effusion and/or pneumothorax). BraveCX uses an artificial intelligence algorithm to analyze images for features suggestive of critical findings and provides case-level output available in the PACS/workstation for worklist prioritization or triage. As a passive notification for prioritization-only software tool within standard of care workflow, BraveCX does not send a proactive alert directly to the appropriately trained medical specialists. BraveCX is not intended to direct attention to specific portions of an image or to anomalies other than pleural effusion and/or pneumothorax. Its results are not intended to be used on a stand-alone basis for clinical decision-making.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

BraveCX

K223754

1. **Submission Sponsor**

Bering Ltd

54 Portland Place, 2nd Floor

London

W1B 1DY

United Kingdom

Contact: DROZDOV Ignat
Title: Managing Director

2. **Submission Correspondent**

Stéphan Toupin, Msc

Dawa Medical LLC

7320 NW 12th Street Suite 103 Miami,

Florida, 33126, USA

Email: stoupin@dawamedical.com

Cellphone number: (786) 731-1159

3. **Date Prepared**

March 14, 2023

4. **Device Identification**

Trade/Proprietary Name: BraveCX

Common/Usual Name: BraveCX

Classification Name: Radiological computer aided triage and notification software

Regulation Number: 892.2080

Product Code: QFM, Radiological computer aided triage and notification software

Device Class: Class II

Classification Panel: Radiology

5. Legally Marketed Predicate Device(s)

Primary Predicate

510(k) Number: K211733

DEVICE NAME: Lunit INSIGHT CXR Triage

MANUFACTURER: Lunit Inc.

6. Indication for Use Statement

BraveCX is a radiological computer-assisted triage and notification software that analyzes adult (≥18 years old) chest X-ray images for the presence of pre-specified suspected critical findings (pleural effusion and/or pneumothorax). BraveCX uses an artificial intelligence algorithm to analyze images for features suggestive of critical findings and provides case-level output available in the PACS/workstation for worklist prioritization or triage. As a passive notification for prioritization-only software tool within standard of care workflow, BraveCX does not send a proactive alert directly to the appropriately trained medical specialists. BraveCX is not intended to direct attention to specific portions of an image or to anomalies other than pleural effusion and/or pneumothorax. Its results are not intended to be used on a stand-alone basis for clinical decision-making.

7. Device Description

The company conducted an internal independent testing set to assess the performance of BraveCX. The validation was completed to determine whether a distinction between target findings is properly completed by the subject device. The internal independent testing set contained n=1,209 cases for pleural effusion and n=1,387 cases of pneumothorax, obtained between June 2007 and August 2019 across 14 acute sites in NHS Greater Glasgow and Clyde. Each image corresponded to a single patient. Images were obtained by following industry standards using both mobile and departmental X-Ray equipment. Table 5A lists X-Ray equipment manufacturers included in the training and internal independent testing of the BraveCX device.

Images used in the training, validation, and testing of the subject device were all manually-curated ground truths provided by three board-certified Radiologists with at least 10 years in specialist radiology training. Model training, validation, and testing sets were generated by stratified random partitions of 80%, 10%, and 10% respectively. Each partition was stratified according to the frequency of abnormalities, gender, and View Position. To avoid data leakage, each stratified split contained non-overlapping patient identifiers.

Table 5A – Distribution of device manufacturers used for training and internal validation of the BraveCX device.

Manufacturer	Proportion of DICOMs
GE Healthcare	2%
AGFA	1%
Fujifilm Corporation	70%
KODAK	8%
Phillips Medical Systems	1%
Samsung Electronics	18%

Summary of results:
ROC AUC was 0.96 (95% CI: 0.95 – 0.97) with 82% sensitivity and 95% specificity for pleural effusion.
For pneumothorax, 0.98 ROC AUC (95% CI: 0.98 –0.99), 89% sensitivity, and 97% specificity were reported.

By confirming that the lower bound of ROC AUC exceeds 0.95 and the sensitivity and specificity for both target radiologic findings are above 80%, the performance of the algorithm of BraveCX is validated to demonstrate that the prespecified target performance is satisfied.

Product deployment:
BraveCX is supplied as a licensed Application Programming Interface (API) that can be deployed either as a cloud-based service, directly on premises, or integrated with third-party systems. The system can be configured to work with multiple DICOM storage platforms, including Picture Archiving and Communications (PACS) or other persistent data storage systems.
BraveCX is a Deep Learning Artificial Intelligence (AI) software that analyzes adult (≥18 years old) chest X-ray images for the presence of pre-specified suspected critical findings (pleural

effusion and/or pneumothorax. It uses deep learning to analyze each image to identify features suggestive of pleural effusion and/or pneumothorax.

Upon image acquisition from other radiological imaging equipment (e.g. X-ray systems), Anteroposterior (AP) and Posteroanterior (PA) chest X-Rays are received and processed by BraveCX. Following receipt of an image, BraveCX de-identifies a copy of each DICOM file and analyses it for features suggestive of pleural effusion and/or pneumothorax. Based on the analysis result, the software notifies PACS/workstation for the presence of the critical findings, indicated by "flag" or "(blank)". This allows the appropriately trained medical specialists to group suspicious exams together with potential for prioritization. Chest radiographs without an identified anomaly are placed in the worklist for routine review, which is the current standard of care.

The intended user of the BraveCX software is a health care professional such as radiologist or another appropriately trained clinician. The software does not alter the order or remove cases from the reading queue.

The software output to the user is a label of "flag" or "(blank)" that relates to the likelihood of presence of pneumothorax and/or pleural effusion.

BraveCX platform ingests prediction requests with either attached DICOM images or DICOM UIDs referencing images already uploaded to DICOM storage. The results will be made available via a newly generated DICOM that is stored in DICOM storage or as a JSON file. The DICOM storage component may be a Picture Archiving and Communications (PACS) system or some other local storage platform.

BraveCX works in parallel to and in conjunction with the standard of care workflow to enable prioritized review by the appropriately trained medical specialists who are qualified to interpret chest radiographs. As a passive notification for prioritization-only software tool within standard of care workflow, BraveCX does not send a proactive alert directly to the appropriately trained medical specialists who are qualified to interpret chest radiographs. BraveCX is not intended to direct attention to specific portions or anomalies of an image and it should not be used on a stand-alone basis for clinical decision-making.

BraveCX automatically runs after image acquisition. It prioritises and displays the analysis results through the worklist interface of PACS/workstation. An on-device, technologist notification is generated within 15 minutes after interpretation by the user, indicating which cases were prioritized by BraveCX in PACS. The technologist notification is contextual and does not provide

any diagnostic information. The on-device, technologist notification is not intended to inform any clinical decision, prioritization, or action.

8. Substantial Equivalence Discussion

The following table compares BraveCX to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Table 5B – Comparison of Characteristics

Manufacturer	**Bering Ltd**	**Lunit Inc.**
Trade Name	**BraveCX**	**Lunit INSIGHT CXR Triage**
510(k) Number	NA	K211733
Product Code	QFM	QFM
Regulation Number	892.2080	892.2080
Regulation Name	Radiology	Radiology
Indications for Use	BraveCX is a radiological computer-assisted triage and notification software that analyzes adult (≥18 years old) chest X-ray images for the presence of pre-specified suspected critical findings (pleural effusion and/or pneumothorax). BraveCX uses an artificial intelligence algorithm to analyze images for features suggestive of critical findings and provides case-level output available in the PACS/workstation for worklist prioritization or triage. As a passive notification for prioritization-only software tool within standard of care workflow, BraveCX does not send a proactive	Lunit INSIGHT CXR Triage is a radiological computer-assisted triage and notification software that analyzes adult chest X-ray images for the presence of pre-specified suspected critical findings (pleural effusion and/or pneumothorax). Lunit INSIGHT CXR Triage uses an artificial intelligence algorithm to analyze images for features suggestive of critical findings and provides case-level output available in the PACS/workstation for worklist prioritization or triage. As a passive notification for

Manufacturer	Bering Ltd	Lunit Inc.
Trade Name	**BraveCX**	**Lunit INSIGHT CXR Triage**
	alert directly to the appropriately trained medical specialists. BraveCX is not intended to direct attention to specific portions of an image or to anomalies other than pleural effusion and/or pneumothorax. Its results are not intended to be used on a stand-alone basis for clinical decision-making.	prioritization-only software tool within standard of care workflow, Lunit INSIGHT CXR Triage does not send a proactive alert directly to the appropriately trained medical specialists. Lunit INSIGHT CXR Triage is not intended to direct attention to specific portions of an image or to anomalies other than pleural effusion and/or pneumothorax. Its results are not intended to be used on a stand-alone basis for clinical decision-making.
Notification-only, parallel workflow tool	Yes	Yes
User	Appropriately trained medical specialists who are qualified to interpret chest radiographs	Appropriately trained medical specialists who are qualified to interpret chest radiographs
Targeted clinical condition, anatomy, and modality	Pleural effusion, pneumothorax Chest/Lung Frontal Chest X-ray	Pleural effusion, pneumothorax Chest/Lung Frontal Chest X-ray
Algorithm for pre-specified critical findings detection	BraveCX is a Deep Learning Artificial Intelligence (AI) software that was trained to detect pleural effusion and pneumothorax in chest X-Ray images. BraveCX uses a vendor agnostic algorithm compatible with DICOM chest X-Ray images	Lunit INSIGHT CXR is deep learning based software that assists radiologists or clinicians in the interpretation of chest x-ray. AI algorithm designed to detect pleural effusion and pneumothorax in chest X-ray images. Lunit INSIGHT CXR Triage uses a vendor agnostic algorithm compatible with DICOM chest X-ray images

Manufacturer	**Bering Ltd**	**Lunit Inc.**
Trade Name	**BraveCX**	**Lunit INSIGHT CXR Triage**
Radiological images format	DICOM	DICOM
Computational Platform	BraveCX is supplied as a licensed Application Programming Interface (API) that can be deployed either as a cloud-based service, directly on premises, or integrated with third-party systems.	Lunit INSIGHT CXR Triage is designed as a software module that can be deployed on several computing and X-ray imaging platforms such as radiological imaging equipment, PACS, On Premise or On Cloud.
Device output in case of positive detection	BraveCX automatically runs after image acquisition. The user may prioritize reporting tasks by grouping images flagged by BraveCX together. Results are displayed through the worklist interface of PACS/workstation No markup on original image. Secondary capture of the finding. Upon image acquisition from other radiological imaging equipment (e.g. X-ray systems), an on-device, technologist notification indicating which cases were flagged in the Secondary Capture image by Brave CX in PACS, is generated 15 minutes after interpretation by the user. The on-device notification is contextual and does not provide any diagnostic information. It is not intended to inform any clinical decision, prioritization, or action to the technologist.	Lunit INSIGHT CXR Triage automatically runs after image acquisition and prioritizes and displays the analysis result through the worklist interface of PACS/workstation. No markup on original image. Secondary capture of the finding. Upon image acquisition from other radiological imaging equipment (e.g. X-ray systems), an on-device, technologist notification indicating which cases were flagged in the Secondary Capture image by Lunit INSIGHT CXR Triage in PACS, is generated 15 minutes after interpretation by the user. The on-device notification is contextual and does not provide any diagnostic information. It is not intended to inform any clinical decision, prioritization, or action to the technologist.

Manufacturer	Bering Ltd	Lunit Inc.
Trade Name	**BraveCX**	**Lunit INSIGHT CXR Triage**
Notification (i.e., recipient, timing and means of notification)	Passive notification. Images with suspicion are flagged in PACS/workstation.	Passive notification. Images with suspicion are flagged in PACS/workstation.
Where generated results (i.e., DICOM files) are stored	Picture Archiving and Communications (PACS) system or some other local storage platform	PACS/Workstation
Performance level – Timing of notification	The average time taken for the notification to travel from the BraveCX API to the point at which the result is displayed in the destination PACS/RIS/EPR worklist is 10.4 seconds.	The average time taken for the notification to travel from the Lunit INSIGHT CXR Triage to the point at which the result is displayed in the destination PACS/RIS/EPR worklist is 14.66 seconds.
Performance level – accuracy of classification	**Pleural Effusion** ROC AUC > 0.95 AUC: 0.988 (95% CI: [0.988, 0.9887] Sensitivity 92.62% (95% CI : [90.67%, 94.27%]) Specificity 98.11% (95% CI [97.33%, 98.71%]) **Pneumothorax** ROC AUC > 0.95 AUC : 0.972 (95% CI: [0.9727, 0.9729]) Sensitivity 93.38% (95% CI: [92.23%, 94.40%]) Specificity 97.27% (95%CI: [96.49%-97.92%])	**Pleural Effusion** ROC AUC > 0.95 AUC: 0.9686 (95% CI: [0.9547, 0.9824]) Sensitivity 89.86% (95% CI: [86.72, 93.00]) Specificity 93.48% (95% CI: [91.06, 95.91]) **Pneumothorax** ROC AUC > 0.95 AUC: 0.9630 (95% CI: [0.9521, 0.9739]) Sensitivity 88.92% (95% CI: [85.60, 92.24]) Specificity 90.51% (95% CI: [88.18, 92.83])

9. Non-Clinical Performance Data

The performance of BraveCX was validated by non-clinical tests. All verification testing met the acceptance criteria (passed), demonstrating that the software fulfills its requirement specifications.

As part of demonstrating safety and effectiveness of BraveCX and in showing substantial equivalence to the predicate devices that are subject to these 510(k) submissions, Bering Ltd completed non-clinical performance tests.

The BraveCX meets all the requirements confirming that the design output meets the design inputs and specifications for the device. BraveCX passed all the testing of the subject device according to Software verification and validation testing per IEC 62304/FDA Guidance.

The company conducted an external independent testing to assess the performance of BraveCX. The studies were conducted with MIMIC Chest X-ray (MIMIC-CXR) Database v2.0.020, NIH Chest X-Ray dataset (NIH-CXR), and CheXpert dataset (Stanford Hospital) that represent the US population.

The datasets contained 867 cases for pleural effusion and 2,114 cases for pneumothorax obtained from Beth Israel Deaconess Medical Center in Boston, MA, NIH Clinical Center, and Stanford Hospital. In all cases, each image corresponded to a single patient. Patients with multiple studies were excluded from the performance validation process. All images were manually labelled by three board-certified Radiologists with at least 10 years of experience in specialty radiology training.

Demographic characteristics of images used in clinical validation studies of BraveCX are shown in the tables (Table 5C, 5D) and reflect a diverse range of ages, gender, and ethnicities.

Table 5C - Demographic characteristics of patients in the clinical validation cohort of the Pleural Effusion classifier.

Characteristic	**MIMIC (Pleural Effusion)**	**NIH (Pleural Effusion**	**CheXpert (Pleural Effusion)**
Gender			
Male	54%	58%	55%
Female	46%	42%	45%
Ethnicity			
Asian	3%	N/A	12%

Black	10%	N/A	6%
Hispanic	3%	N/A	4%
Other/Unknown	30%	N/A	25%
White	54%	N/A	53%
Age			
18-25	2%	9%	9%
25-35	4%	16%	8%
35-65	33%	63%	47%
>65	59%	12%	36%

Table 5D - Demographic characteristics of patients in the clinical validation cohort of the Pneumothorax classifier.

Characteristic	**MIMIC (Pneumothorax)**	**NIH (Pneumothorax**	**CheXpert (Pneumothorax)**
Gender			
Male	60%	58%	53%
Female	40%	42%	47%
Ethnicity			
Asian	5%	N/A	10%
Black	10%	N/A	7%
Hispanic	3%	N/A	2%
Other/Unknown	5%	N/A	25%
White	77%	N/A	56%
Age			
18-25	4%	9%	8%

25-35	7%	16%	7%
35-65	48%	63%	43%
>65	41%	12%	42%

Summary of results:

For pleural effusion, the results are as follows:

A total of n=2,509 images were included in the analysis (n=867 Pleural Effusion).
ROC AUC 0.988 (95% CI:0.9885-0.9887)
Sensitivity 92.62% (95% CI:90.67%-94.27%)
Specificity 98.11% (97.33%-98.71%).

Model performance was unaffected by chest X-ray View Position (anteroposterior or posteroanterior), patient sex, age quartiles (18-53, 53-65, 65-75, ≥75), BMI quartiles (8-25, 25-30, 30-35, and ≥35), and ethnicities (Asian, Black, Hispanic, Other, and White) DeLong's p-values 0.89 – 0.98

The performance for the predicate device indicated for pleural effusion (Lunit INSIGHT CXR Triage, K211733) are as follows: ROC AUC 0.9686 (95% CI: 0.9547 - 0.9824), sensitivity 89.86% (95% CI: 86.72 - 93.00) and specificity 93.48% (95% CI: 91.06 - 95.91).

For pneumothorax, the results are as follows:

A total of n=3,245 images were included in the analysis (n=2,114 Pneumothorax).
ROC AUC 0.972 (95% CI:0.9727-0.9729)
Sensitivity 93.38% (95% CI:92.23%-94.40%)
Specificity 97.27% (96.49%-97.92%).

Model performance was unaffected by chest X-ray View Position (anteroposterior or posteroanterior), patient sex, age quartiles (18-53, 53-65, 65-75, ≥75), BMI quartiles (8-25, 25-30, 30-35, and ≥35), and ethnicities (Asian, Black, Hispanic, Other, and White) DeLong's p-values 0.07 – 0.98.

As compared the device performance time of the BraveCX with the predicate device (Lunit INSIGHT CXR Triage, K211733), the result was comparable with the predicate device.

The performance data show that the lower bound of ROC AUC exceeds 0.95 and the lower bounds of both sensitivity and specificity are above 0.85 for both pleural effusion and pneumothorax. Accordingly, the BraveCX is demonstrated to achieve effective image analysis and triage capabilities.

With regards to the device performance time, the company assessed the performance time of the BraveCX that reflects the time it takes for the device to analyze the study and send a notification to the worklist.

Time-to-notification of BraveCX was 4.8 seconds-10.4 seconds (95% CI: 4.2-10.41s) for simultaneous prediction of Pleural Effusion and Pneumothorax.
The performance for the predicate device (Lunit INSIGHT CXR Triage, K211733) indicated are as follows: The performance time was 20.76 seconds (95% CI: 20.23 - 21.28) for pleural effusion and 20.45 seconds (95% CI: 19.99 - 20.92) for pneumothorax.
As compared the device performance time of the BraveCX with predicate device (Lunit INSIGHT CXR Triage, K211733), the result was comparable with the predicate device.

In summary, the BraveCX performed successfully in the external standalone study.
The BraveCX established standalone adequate detection performance and device performance time for pleural effusion and pneumothorax as compared to the predicate device.

Results of the clinical investigation support the indications for use of BraveCX. External standalone study conclusion confirms that BraveCX is safe and effective as used according to the instructions for use.

10. Statement of Substantial Equivalence

The BraveCX is as safe and effective as the predicate devices. The BraveCX has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices.

The minor technological differences between the BraveCX and its predicate device raise no new issues of safety or effectiveness. The clinical and non-clinical performance data demonstrates that the BraveCX is as safe and effective as the predicate device. Thus, the BraveCX support a decision is substantially equivalent to its predicate devices for triage and notification.

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise additional questions regarding its safety and effectiveness as compared to the predicate device.
BraveCX, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device.